Department of Pesticide Regulation

Paul E. Helliker
Director

Gray Davis
Governor

Winston H. Hickox
Secretary, California Environmental Protection Agency

M E M O R A N D U M

TO: Ann Prichard **HSM-02006**
Senior Environmental Research Scientist (Specialist)
Pesticide Registration Branch

FROM: Thomas Thongsinthusak
Staff Toxicologist (Specialist)
Worker Health and Safety Branch
(916) 445-4267

VIA: Joseph P. Frank
Senior Toxicologist
Worker Health and Safety Branch

DATE: January 28, 2002

SUBJECT: BRAND NAME: Metam-Sodium
ACTIVE INGREDIENT: Metam-Sodium
COMPANY NAME: Metam-Sodium Task Force
TRACKING ID NUMBER: SBRA 181795E
RECORD NUMBER (RN): Not assigned
DATA PACKAGE NUMBER (DPN): Not assigned
EPA REGISTRATION NUMBER: Not available
TITLE: Response to Comments of the Metam-Sodium Task Force on the California Department of Pesticide Regulation's Exposure Assessment Document for Metam-Sodium

On February 11, 2000, David A. Sullivan of the Metam-Sodium Task Force (MSTF) submitted comments on the Department of Pesticide Regulation's (DPR's) "Final Draft Risk Characterization (August 20, 1999) and Exposure Assessment Document for Metam-Sodium (March 24, 1999)." This memo addresses comments concerning exposure assessment of metam-sodium. These comments were reviewed and incorporated in the current exposure assessment document (HS-1703) whenever they are applicable. Comments from the MSTF and responses are as follows:

1. Comment: The Enzone study cannot properly be used as surrogate data for estimating metam-sodium exposure. From the description of the Enzone study in the available DPR documents, it is apparent that the protective measures against occupational exposures used in that study afforded much less protection than the personal protective equipment and application restrictions currently required for metam-sodium application. Considering likely differences in personal protective equipment and application methods, dermal exposures to metam-sodium (assuming they occur at all) could be at least an order of magnitude below those estimated from the Enzone study.

Response: The MSTF has not suggested an appropriate surrogate study for metam-sodium. The author of the exposure document considered that the Enzone study is the only available and suitable surrogate study for metam-sodium exposure assessment because of their similarity in application methods and the unstable nature of parent compounds. An exposure study using metam-sodium is difficult, if not impossible. The MSTF should find out if a method could be developed and tested so that metam-sodium could be collected and analyzed without using a surrogate chemical.

During the Enzone study, the mixers/loaders wore coveralls over normal work clothing, rubber or neoprene boots, and rubber or neoprene gloves, whereas, applicators wore normal work clothing, rubber or neoprene boots, and rubber or neoprene gloves. Under the work clothing, workers wore long underwear, which served as the dermal sampling matrix. These requirements on clothing protection are similar to those required for loaders of metam-sodium. A mixer/loader of metam-sodium is also required to wear a properly fit-tested MSHA/NIOSH-approved half-face respirator with organic vapor cartridges plus nonventing chemical goggles, or an MSHA/NIOSH-approved full-face respirator with organic vapor cartridges. The respiratory protection is intended for protection of metam-sodium degradates, including MITC. Inhalation exposure to metam-sodium was not determined in the exposure document.

Almost all samples collected for analysis showed that residues of cesium ion (a surrogate chemical) were either below the limit of detection (LOD) or the limit of quantitation (LOQ). When cesium was not detected in the underwear sample, the value observed was considered 1/2 LOD and values that were above the LOD but were too low to be quantified were expressed as 1/2(LOD+LOQ). If metam-sodium was used and residues were not detected, half of the LOD or LOQ would be used to estimate exposure.

Methods of applications for Enzone were furrow, above ground drip, and mini-sprinklers. Metam-sodium is intensively used in agriculture more than Enzone. Large overhead sprinkler irrigation systems are routinely used for the application of metam-sodium. Based upon this notion, dermal exposures to metam-sodium shown in the exposure document are likely under estimated.

2. Comment: The RCD estimates dermal absorption to be 2.5 percent based on dermal absorption studies in rats. While the Task Force agrees that the dermal absorption of metam-sodium and/or its degradates has been demonstrated to be 2.5 percent in rats, an *in vitro* rat/human dermal absorption comparison study demonstrates that human skin absorbs metam-sodium (and/or its degradates) at a lower rate of absorption than rats; in fact, up to ten times less at high concentrations.

Response: As shown in the current exposure document, the ratios of *in vitro* dermal absorption between the rat and human skin are dose dependent. The ratio for the high dose (940 $\mu g/cm^2$) was 4.1 and that for the low dose (94 $\mu g/cm^2$) was 1.4. It is likely that the ratio could approach 1.0 when a lower dose level (e.g. 8.6 $\mu g/cm^2$) was used. The low dose was employed in the *in vivo* dermal absorption study. That means the *in vivo* dermal absorption in humans at the dose of 8.6 $\mu g/cm^2$ would be approximately 2.5%. Therefore, the dermal absorption of 2.5% is appropriate for use in the exposure assessment of metam-sodium.

Presently, DPR does not derive *in vivo* dermal absorption in humans from the dermal absorption ratio of *in vitro* rat and human skin, and *in vivo* rats because such method has not been fully validated.

3. Comment: DPR has not provided supporting information to justify the assumption of 50% degradation of metam-sodium on the skin.

Response: Previously, the author of the exposure document arbitrarily reduced dermal exposure of metam-sodium 50 percent based upon the chemical properties of metam-sodium on the skin. Since there was no study to verify the reduction of dermal exposure, the 50 percent dermal exposure reduction is no longer applied in the current version (January 28, 2002).

cc: Susan Edmiston, Senior ERS